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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,534	04/15/2004	G. Ian Rowlandson	IT140825 (5024-00118)	8247

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EXAMINER

ROSENZWEIG, JASON

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,534

Applicant(s)

ROWLANDSON, G. IAN

Examiner

Jason E. Rosenzweig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05242004, 05242004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 05/24/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but references, which were crossed out therein, have not been considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not adequately define how a sudden cardiac death risk score is calculated.

Claim Rejections - 35 USC § 102

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 10-11, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapland (US 5042497) et al.

5. Regarding claims 1 and 18, Shapland discloses a method of predicting sudden cardiac death in a patient (Col 1, Ln. 26-34), the method comprising acquiring patient data from a plurality of medical equipment databases (Col. 2, Ln. 25-28), and further providing a prediction when a patient is at an elevated risk of a sudden death cardiac arrhythmia (Col 1, Ln. 39-40; Col. 3, Ln. 41-42). The examiner acknowledges that a database can read on any data storage device that might be used to store the ECG and neural activity data over a period of time.

6. Regarding claims 2, and 11, Shapland discloses the method of claim 1, and further comprising generating multiple independent indications of sudden cardiac death based on the patient data acquired from the plurality of medical equipment databases (Col 3, Ln. 60-65).

7. Regarding claim 10, Shapland discloses the method of claim 1 and further comprising including at least one of electrocardiogram, data, image data, and sudden cardiac death risk score in a single report (Col. 3, Ln. 48-54).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerrero (US 6,370,423) et al.

11. Regarding claims 1, 2, 3, 4 and 6 Guerrero discloses: A method of predicting sudden cardiac death in a patient, wherein his device is capable of acquiring data from a plurality of medical devices which utilize waveform data and further analyzing the patent data to determine the risk of sudden cardiac death. Guerrero also mentions comparing image patterns (Col 3, Ln 24, and 33) as a means for diagnosis of the risk of sudden cardiac death (Col 15, Ln. 40) using a Computerized Visual Analysis Technique (Col. 17, Ln. 7). Guerrero also discloses a template matching method for detecting

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arrhythmia using millivolt range changes in the QRS (Col 10, Ln. 14). Guerrero also mentions the use of internal correlation dealing with morphologic patterns which would inherently include "measurements to some sort of range" in order to determine an image correlation. Guerrero does not specifically mention the use of a database however the examiner takes official notice that to utilize a database to store information would be of ordinary skill in the art.

12. Regarding claim 5, Guerrero significantly discloses the claimed invention of claim 1, and further discloses comparing electrocardiogram data to stored electrocardiogram patterns to determine an electrocardiogram measurement (Col 23, Ln. 17).

13. Regarding claims 7, and 8, Guerrero significantly discloses the claimed invention of claim 1, and further discloses determining a mathematical measurement based on a parameter value (Col 12, Ln. 2,3; Col 18, Ln. 39; Col 27, Ln. 8). Wherein a parameter value could be anything including a biological parameter, including tissue impedance, or a hardware parameter such a line resistance. Guerrero also discloses the use and or disadvantage of using certain mathematical autocorrelation techniques (Col 17, Ln. 43). It would be obvious to one of ordinary skill in the art to compare a mathematical measurement to a range to determine a mathematical correlation, as this is common modeling techniques in the field of engineering.

14. Regarding claim 9, Guerrero discloses different methods of diagnosing a patient using image correlation, electrocardiogram correlation, and mathematical correlation. It would be obvious to one of ordinary skill in the art to combine different methods of data correlation. The examiner also takes official notice that the act of correlating data would

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be of ordinary skill in the art unless a new correlation technique is specifically addressed.

15. Claims 1,12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 6,261,230) et al.

16. Regarding claims 1,10,12 and 20, Bardy discloses: A medical device comprising a computer program embodied by a computer readable medium as capable of being executed by a computer, the computer program for use in sudden cardiac death (Col 1, Ln. 44) prediction system, the computer program comprising: an acquisition module (Fig 3, Element 51) that communicates over a network (Fig 3, Element 33) to acquire patient data (Fig. 3, Element 50) from a plurality of medical device equipment databases (Fig. 3, Element 52; Fig 1, Element 17). Bardy does not specifically disclose a system used specifically as a sudden cardiac death prediction system but rather a telemetry system used as a patient care system. It would be obvious to one of ordinary skill in the art to translate this technology into a device specifically used as a sudden cardiac death prediction system which utilized electrocardiograph information from a external machine rather than a implanted medical device in order to have a device capable of predicting sudden cardiac death which does not have to be implanted within the body.

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 6,261,230) in view of Selker (US 5276612).

18. Regarding claim 13, Bardy discloses the computer program of claim 12, however does not specify a report module which outputs at least one of electrocardiogram data,

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an electrocardiogram measurement, image data, an image patter, an image correlation, an image measurement, a diagnosis, a recommended treatment, a recommended follow-up test, a mathematical measurement, a range, and a physician identifier. Selker discloses a risk management system used with cardiac patients, which provides a report module, which reports electrocardiograph findings, which includes mathematical measurements (Col. 4, Ln. 29), a range (Col. 4, Ln. 4), Recommended treatment (Col. 4, Ln. 66), Diagnoses (Col. 4, Ln. 59). It would be obvious to one of ordinary skill in the art to modify Bardy's disclosure to create a system and method for the prediction of sudden cardiac death by including a system capable of quantitatively reporting findings of an electrocardiogram rather than using data from a implantable ICG so that a diagnostic test could be performed on a patient with out requiring a implantable medical device.

19. Regarding claim 17, Bardy discloses a computer program stored on a tangible medium (Col 8, Ln. 51), however does not specify a report module which outputs at least one of electrocardiogram data, an electrocardiogram measurement, image data, an image patter, an image correlation, an image measurement, a diagnosis, a recommended treatment, a recommended follow-up test, a mathematical measurement, a range, and a physician identifier. Selker discloses a risk management system used with cardiac patients, which provides a report module, which reports electrocardiograph findings, which includes mathematical measurements (Col. 4, Ln. 29), a range (Col. 4, Ln. 4), Recommended treatment (Col. 4, Ln. 66), Diagnoses (Col. 4, Ln. 59). It would be obvious to one of ordinary skill in the art to modify Bardy's disclosure to create a system

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and method for the prediction of sudden cardiac death by including a system capable of quantitatively reporting findings of a electrocardiogram and displaying the results in a report for review by medical personnel so that the technology could be used without a implantable medical device.

20. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 6,261,230) in view of Feng (US 5509425).

21. Regarding claims 14,15 and 19, Bardy discloses a system and method comprising of computer executable code facilitating a automated collection and analysis patient care system which including detecting signs of Sudden Cardiac Death as recited in claim 12. Bardy does not disclose of a pattern recognition module, wherein the pattern recognition module accessing at least one of electrocardiogram patterns and image patterns. Feng discloses an arrangement and method of diagnosing and warning of a heart attack which includes a pattern recognition module (Fig .16) accessing at least one of electrocardiogram patterns and image patterns (Fig 16) wherein an image pattern could be a waveform (Figs. 6-12). It would be obvious to one of ordinary skill in the art to modify Bardy's disclosure to include a pattern recognition module as disclosed by Fend to facilitate in the detection of sudden cardiac death.

22. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 6,261,230) in view of Elghazzawi (5,819,007).

23. Regarding claim 16, Bardy discloses a system and method comprising of computer executable code facilitating a automated collection and analysis patient care system which including detecting signs of Sudden Cardiac Death as recited in claim 12

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but does not mention the use of a decision support module. Elghazzawi discloses the use of feature based expert system classifier and their use as a decision support system and how they can be effective in detecting arrhythmia. Elghazzawi does not disclose of a particular acquisition module rather disseminating data to develop a decision support systems, specifically in detecting arrhythmia. It would be obvious to one of ordinary skill in the art to modify Bardy's disclosure to include a decision support system, which includes an algorithm to detect sudden cardiac death using existing knowledge and facts from historical, and presently acquired medical data in order to aid in the detection of sudden cardiac death.


Conclusion

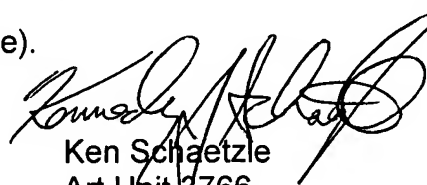
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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